K021978

Nishitomo Co., Ltd. 449-3 Hiruda, Tamaki-cho, Watarai-gun Mie-pref. 519-0423 JAPAN

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center (HFZ-401)
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APR 0 8 2003

510(k) Summary

Submitter's Name:	Kinji Nishimura Nishitomo Co., Ltd.
Address:	449-3 Hiruda, Tamaki-cho, Watarai-gun Mie-prefecture, 519-0423 JAPAN
Phone:	++81-596-58 6987
Fax:	++81-596-58-6968
E-mail:	sophia@taionkei.com
Contact:	Lloyd Duplantis(Official Correspondent)
Trade Name:	**Petit Sophia**, Computerized Basal Body Thermometer Model No. BT-14E
Classification:	Device, Fertility Diagnostic, Proceptive Product Code: LHD Registration No.: None Class: II
Predicate Device:	Nishitomo, L Sophia, BT-01 K 901512
Device Description:	This device is the clinical thermometer with memory the following functions.

(1) Alarm clock function for measuring temperature at constant time.
(2) Measuring accuracy within +/-0.05℃(between 35.00℃ and 38.00℃)
+/-0.1℃(between 34.00℃ and 35.00℃,
38.00℃ and 40.00℃)
(3) Displaying the measured temperature precisely, generating the measurement completion signal(buzz) and warning of a measuring error by buzzer, in case happened.
(4) Memory capacity of data for 6 menstrual cycles or 210 days.
(5) Displaying the measured temperature value in graph.
(6) Transferring the stored data to an external instrument.

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Intended Use:

The **Petit Sophia** Basal Body Thermometer is intended for measuring, and recording basal body temperature (BBT) as an aid in ovulation prediction to aid in conception (not to be used for contraception).

Technological Characteristics:

The **Petit Sophia** Basal Body Thermometer has the same general design and performance characteristics as the predicate device "L-Sophia", which is manufactured by the same company Nishitomo Co., Ltd. The main difference is the physical size, shape, weight and temperature display. The **Petit Sophia** Basal Body Thermometer has the same intended use, general design and incorporates similar materials and components, hence should therefore raise no new questions of safety and effectiveness. This submitter concludes that the **Petit Sophia** Basal Body Thermometer is therefore substantially equivalent to the predicate device "L-Sophia, BT-01, K 901512".

Purpose of Submission:

The **Petit Sophia** Basal Body Thermometer, manufactured by Nishitomo Co., Ltd., Japan, is a new device intended to be marketed in the USA.

The **Petit Sophia** Basal Body Thermometer is similar to another Basal Body Thermometer, approved and marketed in the USA, as the predicate device mentioned below.

Predicate Device:

Nishitomo, L-Sophia, BT-01
K 901512(Predicate device)

U.S. Contact:

Lloyd J. Duplantis, Jr., P.D.(Official Correspondent)
Remedies Apothecary, Inc
3696 West Main Street
Gray, LA 70359
Tel: 985-872-4547 Fax: 985-580-0213
E-Mail: lloydrem@bellsouth.net

Sincerely yours,

11-29-2002
Date(mm/dd/yy)

Kinji Nishimura
President
Nishitomo Co., Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 0 8 2003

Nishitomo Co., Ltd.
% Mr. Lloyd Duplantis
Remedies Apothecary
3696 West Main Street
GRAY LA 70359

Re: K021978
Device Name: Petit Sophia, Electronic Basal Body Thermometer
Regulation Number: None
Regulatory Class: Unclassified
Product Code: 85 LHD
Dated: March 12, 2003
Received: March 17, 2003

Dear Mr. Duplantis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K021978

Device Name: PETIT SOPHIA

Indications For Use:

For measuring, and recording basal body temperature(BBT) as an aid in ovulation prediction to aid in conception (not to be used for contraception).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021978

Prescription Use ___ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2